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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,472	12/14/2001	Christopher Kern	02481.1767	1068

7590 08/24/2004

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Washington, DC 20005-3315

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,472	KERN ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03162004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 6 dated December 19, 2002 is acknowledged.

Applicant's Response Dated May 17, 2004

2. In the Response filed May 17, 2004, claims 1, 3, and 6-7 were amended; claims 9-18 were canceled; and claims 19-25 were added.
3. Claims 1, 3-8, and 19-25 are pending. An action on the merits of claims 1, 3-8, and 19-25 is contained herein below.
4. The rejection of claims 1 and 3-8 under 35 U.S.C. 112, first paragraph, has been rendered moot in view of applicant's amendment dated May 17, 2004.
5. The rejection of claims 1 and 3-8 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendment dated May 17, 2004.
6. The rejection of claims 1 and 3-8 under 35 U.S.C. 102(b) as being anticipated by Yeda Research and Development WO 92/19249 (Yeda) is maintained for the reasons of record as set forth in the Office Action dated February 18, 2004.

Objections/Rejections of Record Set Forth in Office Action

Dated February 18, 2004

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeda Research and Development WO 92/19249 (Yeda).

Yeda discloses the administration of low molecular weight heparin (LMWH) compositions for the prevention and/or treatment of pathological process involving the induction of TNF- α secretion (page 7, lines 9-30; page 8, lines 1-6; page 11, lines 27-34). LMWH disclosed by Yeda includes enoxapirin in doses of 20 mg / 0.2 ml and 40 mg / 0.4 ml of water. The compositions are administered in any manner as dictated by the particular application at hand including, but not limited to, enteral administration (including oral) or parenteral administration (including topical or inhalation with the aid of aerosols). In preferred embodiments, the compositions are administered subcutaneously or intravenously.

9. Applicant's arguments filed May 17, 2004 have been fully considered but they are not persuasive. Applicant argues that Yeda does not teach treating any of the disorders contemplated by the instant method (i.e. degenerative joint disorder, connective tissue disorder, wound healing disturbance, etc.)

The examiner respectfully disagrees. Applicant's attention is directed pages 12-13 of Yeda wherein the treatment of disorders linked in pathological processes involving induction of TNF- α secretion is disclosed. The disorders

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include atherosclerosis and vasculitis and pathological processes related thereto; autoimmune diseases, e.g., rheumatoid arthritis, diabetes type I; allergy; graft rejection; and acute and chronic inflammatory diseases, e.g. uveitis, bowel inflammation.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure as originally filed does not disclose a method of preventing the recurrence of a disorder comprising administering to a subject a therapeutically effective amount of enoxaparin. The newly added claims are directed to a narrower population (subjects previously diagnosed with a degenerative joint disorder, connective tissue disorder, wound healing disturbance, disorder of the locomotor system, or disturbance of bone metabolism). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph.

Conclusion

12. Claims 1, 3-8, and 19-25 are pending. Claims 1, 3-8, and 19-25 are rejected. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD
Examiner
Art Unit 1623


Dr. Samuel Barts
Primary Patent Examiner
Technology Center 1600

ptl
August 18, 2004